MAY 2 4 2002

K021409

510(k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Identification: At HOME OVULATION TEST (Model 9032)

Description: Immunoassay for the qualitative detection of LH in urine.

Name of Manufacturer: Phamatech
9530 Padgett Street
Suite #101
San Diego, California 92126, USA

Intended Use: The At HOME OVULATION TEST is a rapid, qualitative immunoassay for the detection of luteinizing hormone (LH) in urine. The cut-off concentration for this test is as follows: LH at 30mIU/mL. This assay is intended for use in the home to assist in determining the ovulation cycle.

Technology: The At HOME OVULATION TEST, like many commercially available ovulation test kits, qualitatively measures the presence of luteinizing hormone by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Phamatech (San Diego, CA) OvuCard and the Quidel OvuQuick LH Test (San Diego, CA 92121). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / LH / colored (labeled) antibody complexes.

Performance: The product performance characteristics of the At HOME OVULATION TEST were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the Phamatech At HOME OVULATION TEST to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of luteinizing hormone in urine. Correlation studies, using clinical specimens, produced a >99% correlation when compared to the Syntron Be Sure Test. Clinical studies, performed at two independent laboratories, were also performed. In them the Phamatech At HOME OVULATION TEST exhibited excellent overall accuracy (>98%) in the hands of professional users. A consumer study was also performed, in it the At HOME OVULATION TEST exhibited excellent overall accuracy. Consumer interpretation of the LH test showed accuracy to be _____or 97.0%

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech At HOME OVULATION TEST is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Carl A. Mongiovi
Vice President
Pharmatech, Inc.
9530 Padgett Street – Suite #101
San Diego, CA 92126

MAY 2 4 2002

Re: k021409
Trade/Device Name: At Home Ovulation Test (Model 9032)
Regulation Number: 21 CFR 862.1485
Regulation Name: Luteinizing hormone test system
Regulatory Class: Class I
Product Code: CEP
Dated: April 25, 2002
Received: May 3, 2002

Dear Mr. Mongiovi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K021409

Device Name: At Home Ovulation Test (Model 9032)

Indications for Use:

The Phamatech At Home Ovulation Test is a rapid qualitative test for the detection of luteinizing hormone (LH) in urine. It is intended for over the counter use.

PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of the CDRH Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021409

Division Sign-off
Division of Clinical Laboratory Devices
510 (k) Number:

Prescription Use:_____ OR Over the Counter: ✓
Per 21 CFR 801.109